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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/031,531 | 04/15/2002 | Neil R. Anderson | 29342/36231A | 6194 |

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EXAMINER

TRAN, SUSAN T

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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/031,531 | Applicant(s) ANDERSON ET AL. | |
| | Examiner Susan T. Tran | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,8,9,12-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,8,9,14-20 and 22-24 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. <u>04/14/04</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of applicant's Amendment and Extension of Time filed 10/06/03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 8, 14, 16-20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daugan WO 97/03675.

Daugan teaches orally administering an active compound of formula (I) for the treatment of sexual dysfunction (pages 2-4). The active compound is administered in the form of capsule in an amount of 0.5 to 500 mg daily (page 5, 1st paragraph). The active compound can be in the form of elixirs, liquid, or suspensions; and contains diluents, excipients, carriers, and suspending agent (page 5). Page 15 discloses a capsule formulation comprises active ingredient, polyvinyl pyrrolidone, and magnesium stearate. Daugan also teach the active compound is blended with Labrafil (carrier) in the form of suspension, and the suspension is then filled into soft gelatin capsules (page 16).

Daugan does not specifically teach the claimed solvent as a carrier. However, Labrafil M 1944CS disclosed in page 16 contains polyethylene glycol 300 (PEG 300).

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Thus, it would have been obvious for one of ordinary skill in this art to, by routine experimentation optimize the suspension formulation of Daugan using the claimed solvent with the expectation of providing a composition of active compound of formula (I) in a dosage form suitable for the treatment of sexual dysfunction in male and female.

Claims 1, 4, 8, 14, 16-20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wyllie WO 99/30697, in view of Daugan WO 97/03675.

Wyllie teaches an oral composition comprising active compound of formula I and carrier or diluent for the treatment of male and female sexual dysfunction (pages 8, 11 and 16). The carrier or diluent used in the oral formulation includes polyvinyl pyrrolidone and propylene glycol (page 17). Wyllie teaches the oral composition is in the form of solutions, suspensions and capsule, but is silent as to the teaching that the solutions or suspensions are filled into the capsule.

Daugan teach the use of the same active compound for the same treatment is in suspension that can be filled into soft gelatin capsules (page 16). Therefore, it would have been obvious for one of ordinary skill in the art to modify the solutions or suspensions formulation of Wyllie in the gelatin capsule in view of the teaching of Daugan with the expectation of similar result, because the references teach the use of the claimed compound for the same treatment, *e.g.*, sexual dysfunction.

Claims 1, 4, 8, 9, 14-20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wyllie WO 99/30697 and Daugan WO 97/03675, in view of Brox et al. EP 0 649 651 A1.

Wyllie and Daugan are relied upon for the reasons stated above. To be more significant regarding the specific carrier, such as propylene glycol and polyethylene glycol 400, Brox teaches soft gelatin capsule suitable as a carrier for suspension and/or solution of sparingly soluble drugs (see abstract and page 2). Brox teaches polyethylene glycol having molecular weight from 200-600 and propylene glycol are suitable solvent for the soft gelatin capsule and also for the low soluble drugs (page 3, lines 32 through page 4, lines 1-52). Thus, it would have been obvious for one of ordinary skill in the art to optimize the oral suspension/solution compositions of Wyllie and Daugan using the gelatin composition in view of the teaching of Brox with the expectation of providing a suitable dosage form for the sparingly soluble compound useful for the treatment of sexual dysfunction.

Claims Objection

Claims 12 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Meyer et al. is cited as being of interest for the teaching of gelatin capsule containing sparingly soluble drug in the form of suspension containing PEG having MW from 200-600, including PEG 400.

Response to Arguments

Applicant's arguments filed 10/06/03 have been fully considered but they are not persuasive.

Applicant argues that the examples of the cited references do not disclose or suggest capsule containing solution or suspension. In response to applicant's argument, the cited references are relied upon for the teachings within the four-wall patent; they are not limited to the best mode described in the examples. Nonetheless, Daugan at page 16, example 3 describes a suspension being filled into a soft gelatin capsule. Accordingly, the rejections are maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600